DEPARTMENT OF HEALTH & HUMAN SERVICES
Voice - (312) 886-2359
TDD - (312) 353-5693
(FAX) - (312) 886-1807
http://www.hhs.gov/ocr/

OFFICE OF THE SECRETARY
Office for Civil Rights, Region V
233 N. Michigan Ave., Suite 240
Chicago, IL 60601

March 31, 2009

David McCann
211 West Market Street
Akron, Ohio 44303

Ellen Hodge
Caremark Privacy Officer
P.O. Box 52072 MC-016
Phoenix, AZ 85072-2072

Re: McCann v. Caremark
OCR Transaction Number: 06-61821

Dear Mr. McCann:
Ms. Hodge:

On September 8, 2006, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received a complaint from David McCann alleging that Caremark Rx, Inc. ("Caremark") is not in compliance with the Federal Standards for Privacy of Individually Identifiable Health Information (45 C.F.R. Parts 160 and 164, Subparts A and E, the Privacy Rule). Specifically, Mr. McCann alleges that, in February and May 2006, Caremark disclosed his prescription history, without his authorization, to Michelle Smith, a former Ease@work liaison and Summit County Department of Insurance and Risk Management ("Department of Insurance") Benefits Administrator. These allegations could reflect violations of 45 C.F.R. §§164.502(a) and 164.530(c), respectively.

OCR enforces the Privacy Rule, and also enforces Federal civil rights laws which prohibit discrimination in the delivery of health and human services because of race, color, national origin, disability, age, and under certain circumstances, sex, and religion.

We have reviewed the matter raised in the complaint. On May 23, 2007, OCR notified Caremark of the allegations. Thereafter, Caremark responded to OCR in writing and provided data supporting its response. OCR also reviewed and analyzed data from Mr. McCann, including information submitted in response to an OCR data request. Based on our review of the facts and circumstances of this matter, we have determined that the activities of Caremark do not violate the Privacy Rule.

Caremark is a health care provider that is a covered entity for purposes of the Privacy Rule. Caremark also performs services as a business associate on behalf of other covered entities. In this case, Caremark reported that it administered prescription drug benefits as a business

associate for the Department of Insurance's administration of its employee pharmacy benefits program.[1] During this investigation, OCR received copies of the agreements memorializing the business associate relationship, under which both parties agreed to comply with all applicable state and federal laws and regulations (including HIPAA) relating to the privacy and security of personal health data. Pursuant to the agreements, Caremark permitted access to a limited number of Department of Insurance employees, with individualized identification numbers, to view and manage prescription accounts via Caremark's RxNavigator system. The RxNavigator system is a web-based analytic, decision support, and reporting tool which enables benefit providers, such as the Department of Insurance, to update or view eligibility, perform claims research tied to drug coverage and co-pays, and engage in other functions relating to treatment, payment, and health care operations, as set forth in the Privacy Rule.

For its part, the Department of Insurance informed OCR that five of its employees had access to the RxNavigator system. The Department of Insurance identified Ms. Smith, a former Benefits Administrator, as an employee who had access to the RxNavigator system in order to perform the functions of her job.

PHI may be used or disclosed without an individual's authorization as permitted or required by the Privacy Rule. The Privacy Rule permits the use and disclosure of PHI for treatment, payment, and health care operations. See 45 C.F.R. §§ 164.502(a), 164.506; see also 45 C.F.R. § 164.501 (definitions of treatment, payment, health care operations). The Privacy Rule further allows disclosure of PHI to business associates if the health plan obtains satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under the Privacy Rule. See 45 C.F.R. §§ 164.502(e)(1) and 164.504(e).

In this case, the Department of Insurance contracted with Caremark for pharmacy benefit management services. The business associate agreements provided the assurances required by the Privacy Rule. There is no evidence that Caremark breached these assurances by providing access to its RxNavigator system to certain Department of Insurance employees, or that it disclosed Mr. McCann's PHI without authorization for purposes other than treatment, payment, or healthcare operations. In fact, the terms of the business associate relationship specifically allowed for secure access to the Department of Insurance, and its designated employees, in order to facilitate management of its prescription accounts. Therefore, OCR is closing this complaint, effective the date of this letter, without further action.

OCR's determination as stated in this letter applies only to the allegations in this complaint that were reviewed by OCR.

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[1] According to the terms of agreement, Caremark's contract with Summit County ended on December 31, 2007.

Under the Freedom of Information Act, we may be required to release this letter and other information about this case upon request by the public. n the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

If you have any questions, please contact Kurt Temple, Investigator, at (312) 886-5893 (Voice), (312) 353-5693 (TDD).

Sincerely,

Valerie Morgan-Alston
Regional Manager

For Monday, April 6, 2009

Mr. Timothy J. Menke
Deputy Inspector General for Investigations
Office of Investigations
Office of the Inspector General
United States Department of Health and Human Services
Room 5029
Wilbur J. Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Dear Deputy Inspector General Menke:

RE: McCann V. Caremark 06-61821 / referred to OCR Region V - Chicago

I am not satisfied with the investigative procedures of the Office of Civil Rights and would request that a review of their findings, related to this case, be initiated.

Attached you will find the opinion offered by Office of Civil Rights Region V related to my complaint of August, 2006.

The amount of time in their reaching their conclusion is not satisfactory.

The opinions rendered are not accurate.

To wit:

OCR writes

Specifically, Mr. McCann alleges that, in February and May 2006, Caremark disclosed his prescription history, without his authorization, to Michelle Smith

McCann response
✓Nowhere in my complaint did I identify Michelle Smith as being responsible for the unauthorized access to my pharmaceutical records.

However, I did provide, to Attorney Kurt Temple, a list of individuals responsible for accessing my pharmaceutical records.

✓In my complaint I identify dates of the county illegally accessing my pharmaceutical records.

Nowhere in the OCR response are dates identified as to when my pharmaceutical records were accessed and why.

OCR writes:

The Department of Insurance (Summit County) identified Ms. Smith, a former benefits Administrator, as an employee who had access to the RxNavigator system in order to perform the functions of her job.

McCann response
✓Nowhere does the OCR specifically write that it was Ms. Smith who accessed my records.

✓Nowhere does the OCR confirm her having performed such a function and their seeking her comments as to why, if in fact she accessed my pharmaceutical records, she was asked to perform such a function – and was the purpose for treatment, payment, of healthcare operations.

OCR writes

There is no evidence that Caremark breached these assurances by providing access to its RxNavigator system to certain Department of Insurance employees, or that it disclosed Mr. McCann's PHI without authorization for purpose other ***than treatment, payment, or healthcare operations*** *(emphasis added).*

McCann response:
What treatment? What payment? What relation to health care operations?

My previous correspondence with the Office of the Inspector General – Chicago regarding a review was less than satisfactory as they referred me to the OCR for any questions about investigative procedures.

Sincerely,

David McCann
211 West Market Street
Akron, Ohio 44303
330-864-0169